NDA 021945
ANDAs 211070 211071 210618 210877 208381 210723 210724 211777

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 5, 2020

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Re: Docket No. FDA-2020-N-2029
PROPOSAL TO WITHDRAW MARKETING APPROVAL; NOTICE OF OPPORTUNITY FOR A HEARING

Dear holders of the above-referenced new drug and abbreviated new drug applications:

The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA or Agency) is proposing to withdraw approval of Makena (hydroxyprogesterone caproate injection, 250 milligrams (mg) per milliliter (mL), once weekly), new drug application (NDA) 021945, held by AMAG Pharmaceuticals, Inc. (AMAG). Upon withdrawal of NDA 021945, FDA would also withdraw all abbreviated new drug applications (ANDAs) for drug products containing hydroxyprogesterone caproate that reference NDA 021945 as their referenced listed drug:

- ANDA 211070 and 211071, held by Eugia Pharma Specialties Limited
- ANDA 210618 and 210877, held by Slayback Pharma LLC
- ANDA 208381, held by Sun Pharmaceuticals Industries Ltd
- ANDA 210723 and 210724, held by American Regent, Inc.
- ANDA 211777, held by Aspen Pharma USA Inc.

Withdrawal is warranted because the postmarketing trial required as a condition of Makena's approval failed to verify clinical benefit, because Makena is not shown to be effective under its conditions of use, and for additional reasons described below.

I. Background

On February 3, 2011, FDA approved NDA 021945 for Makena under the accelerated approval pathway (section 506(c) of the Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 356(c), and 21 CFR part 314, subpart H) to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth (PTB).

Eight approved ANDAs referenced Makena as the basis of submission: ANDAs 210724, 210723, 211777, 211071, 210877, 211070, 210618 and 208381.

A. Basis for Accelerated Approval

FDA's accelerated approval pathway expedites the approval, and therefore availability, of drugs that appear to offer a meaningful advantage over available therapy and are intended to treat serious diseases or conditions. For approval, both the traditional and accelerated approval pathways require a drug to have substantial evidence of effectiveness and for its expected benefits to outweigh its potential risks. For traditional approval, effectiveness is based on clinical benefit (such as how a patient survives, functions, or feels) or on a validated surrogate endpoint (one that has been established to predict clinical benefit), whereas accelerated approval is based on a drug's effect on a surrogate or intermediate clinical endpoint that is "reasonably likely . . . to predict [a drug's] clinical benefit."[1] FDA's accelerated approval regulations, included in 21 CFR part 314, subpart H, describe the procedures for accelerated approval and the expedited withdrawal procedures for drugs approved under the accelerated approval pathway. These regulations state that FDA may grant marketing approval "on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity" (§ 314.510). For purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit.[2] An accelerated approval is based on a weighing of the clinical benefit reasonably predicted by the existing data against the known and potential risks of the product.

[1] Section 506(c)(1)(A) of the FD&C Act.

[2] See FDA's guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014) (Expedited Programs Guidance) at 17. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

The Makena NDA relied on evidence from the Maternal Fetal Medicine Unit (MFMU) Network trial (referred to as "Trial 002") for primary support of efficacy and safety. The primary efficacy endpoint in Trial 002 was the proportion of pregnant women delivering prior to 37 weeks gestation, a surrogate endpoint considered reasonably likely to predict clinical benefit to the neonate. In Trial 002, a lower proportion of women in the group receiving Makena delivered prior to 37 weeks than in the group receiving a placebo (37 percent and 55 percent, respectively). This treatment effect appeared independent of race, number of prior preterm deliveries, and gestational age of the prior preterm birth. The proportions of women delivering at <35 and <32 weeks gestation were also statistically lower among women treated with Makena compared to placebo, although the upper bounds of the 95% confidence interval (CI) for these treatment differences were near zero. See Table 1.

Table 1: Efficacy – Trial 002

Proportion of women (%) delivering at gestational age	Makena	Placebo	Treatment difference (95% CI)
<37 weeks	37%	55%	-18 (-28, -7)
<35 weeks	21%	31%	-9 (-19, -0.4)
<32 weeks	12%	20%	-8 (-16, -0.3)

Source: adapted from Table 5 in Makena's prescribing information

The treatment effect was sufficiently persuasive to support approval under subpart H based on the findings of this single adequate and well-controlled trial.

B. Required Postmarketing Study

For a product approved under the accelerated approval pathway, FDA requires that the applicant conduct appropriate postapproval studies to verify and describe the clinical benefit of the product.[3]

FDA's February 3, 2011, approval letter for NDA 021945 described the following postmarketing confirmatory study requirements: (1) completion of a clinical trial of Makena in women with a singleton pregnancy who had a previous spontaneous preterm birth (Protocol #17P-ES-003) (Trial 003); and (2) completion of the clinical follow-up study (Protocol #17P-FU-004) of children born to women who participated in Protocol #17P-ES-003. Ongoing Study 17P-FU-004 is collecting safety data from children through 22 months of age. Trial 003 was intended to verify Makena's expected clinical benefit to neonates, whereas study 17P-FU-004 assesses long-term safety in children and is not considered in the determination of Makena's efficacy.

Trial 003 evaluated the co-primary endpoint of a neonatal composite index (a clinical outcome measuring neonatal morbidity and mortality) and gestational age at delivery (delivery less than 35 weeks gestation, a surrogate endpoint). Trial 003 failed to demonstrate a statistically significant difference between the Makena and placebo arms

[3] Section 506(c)(2)(A) of the FD&C Act; see also 21 CFR 314.510.

for either the proportion of women delivering prior to 35 weeks (11 percent Makena compared to 12 percent placebo, p=0.72) or the proportion of neonates experiencing at least one event comprising the neonatal composite index[4] (5.4 percent for Makena compared to 5.2 percent for placebo, p=0.84). There was also no effect of Makena on the secondary efficacy endpoints of gestational age <37 weeks (which was the primary efficacy endpoint in Trial 002) and gestational age <32 weeks.

C. Legal Standard for Withdrawal

Section 505 of the FD&C Act (21 U.S.C. 355) provides statutory authority for FDA to approve new drug applications and abbreviated new drug applications and withdraw approval of them on certain grounds.

In addition, section 506 of the FD&C Act, added to the statute with the passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and amended by the Food and Drug Administration Safety and Innovation Action of 2012 (FDASIA), describes, among other things, the accelerated approval of new drug applications and the expedited withdrawal procedures that apply to them. FDA has the legal authority to use expedited procedures to withdraw approval of a product that has received an accelerated approval if, among other reasons, "a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit," or "other evidence demonstrates that the product is not safe or effective under the conditions of use." [5] Likewise, the regulations provide that FDA may withdraw an accelerated approval when "[a] postmarketing clinical study fails to verify clinical benefit[,]" or "[o]ther evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use."[6]

Neither the withdrawal provisions of section 506(c) of the FD&C Act nor 21 CFR part 314 subpart H explicitly address the status of ANDAs that rely on a reference listed drug approved under section 505(c) pursuant to section 506(c) when approval of that reference listed drug is withdrawn. Section 505(e) of the FD&C Act includes certain grounds for withdrawal that could apply to an ANDA for reasons specific to the ANDA. In addition, under section 505(j)(6) of the FD&C Act, FDA has the authority to withdraw approval of an ANDA when the listed drug it references was withdrawn for grounds described in the first sentence of section 505(e) or was withdrawn under section 505(j)(6) or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness

[4] The neonatal composite index assesses neonatal morbidity and mortality and includes clinically important diseases and conditions seen in infants born prematurely. The neonatal composite index includes neonatal death, Grade 3 or 4 intraventricular hemorrhage (bleeding in the brain), respiratory distress syndrome, bronchopulmonary dysplasia (abnormal lung development in the infant), necrotizing enterocolitis (bacterial infection in the intestine), and proven sepsis (life-threatening condition caused by the body's response to infection). A neonate with one or more these events of the composite neonatal index counts towards the co-primary endpoint of the proportion of neonates experiencing the neonatal composite index.

[5] Section 506(c)(3)(B) and (C) of the FD&C Act. See also section 505(e)(3) of the FD&C Act (first sentence).

[6] 21 CFR 314.530(a)(1) and (a)(6).

reasons. Thus, under section 505(j)(6), if an ANDA refers to a listed drug that has been withdrawn as described in the previous sentence, withdrawal of the ANDA under section 505(j)(6) will follow. The regulations (21 CFR 314.150 and 314.151) address withdrawal of ANDAs. Specifically, 21 CFR 314.151 addresses withdrawal of ANDAs when approval of the NDA for the reference listed drug is withdrawn. The regulations provide, in part, that the approval of an ANDA "identified in the notice of opportunity for hearing on the withdrawal of a listed drug will be withdrawn when the agency has completed the withdrawal of approval of the listed drug." 21 CFR 314.151(b)(3).

D. Advisory Committee Meeting

On October 29, 2019, FDA convened a meeting of its Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) to consider the findings of Trial 003 in the context of AMAG Pharmaceuticals' confirmatory study obligation and discuss the evidence regarding the effectiveness of Makena in reducing the risk of recurrent PTB and improving neonatal outcomes.[7] All 16 voting members of the BRUDAC concluded that the findings from Trial 003 failed to verify the clinical benefit of Makena on neonatal outcomes. The BRUDAC further concluded, by a vote of 13 to 3, that, based on the findings from Trial 002 and Trial 003, there is not substantial evidence of effectiveness of Makena in reducing the risk of recurrent preterm birth. Nine members of the BRUDAC voted that FDA should pursue withdrawal of Makena from the market, while seven voted that Makena should remain on the market while a new confirmatory trial is conducted.

II. Grounds for Withdrawal

The Agency proposes to withdraw approval of Makena both because the required confirmatory study failed to verify clinical benefit and because the evidence demonstrates that Makena is not shown to be effective under its conditions of use, either of which on its own is a sufficient basis for withdrawal of approval under the statute and regulations. First, the required postmarketing clinical trial, Trial 003, failed to verify clinical benefit — Makena showed no improvement in the neonatal composite index versus placebo. Second, Makena has not been shown to be effective at reducing the risk of recurrent pre-term birth or improving neonatal outcomes. Trial 003 not only failed to demonstrate Makena's benefit to the neonate, but also failed to substantiate any effect of Makena on the surrogate endpoint of gestational age at delivery that was the basis of the initial approval. There are also other reasons that approval should be withdrawn, discussed below.

A. Postmarketing Study Failed to Verify Clinical Benefit

As a condition of Makena's approval, we required the applicant to complete Trial 003 to verify and describe the clinical benefit predicted by the effect on the surrogate endpoint

[7] Information about and materials from this meeting can be found on the webpage entitled "October 29, 2019: Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee Meeting Announcement", at https://www.fda.gov/advisory-committees/advisory-committee-calendar/october-29-2019-meeting-bone-reproductive-and-urologic-drugs-advisory-committee-meeting-announcement.

shown in Trial 002. Not only did Trial 003 fail to verify a clinical benefit of Makena, it also showed that Makena had no effect on the surrogate endpoints studied, i.e., the proportion of women delivering at < 35, < 32, or < 37 weeks of gestational age. See Table 2. The advisory committee unanimously agreed Trial 003 failed to verify clinical benefit. In its March 2020 press release regarding Trial 003, AMAG stated that Trial 003 "did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints," and "[t]here are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity."[8]

Table 2: Efficacy Results – Trial 003

Proportion of subjects (%)	Makena (N=1130)	Placebo (N=578)	Difference (95% CI)	P-value
Neonatal composite index[9]	5.4%	5.2%	0.2% (-2.0%, 2.5%)	0.84
Birth < 35 weeks	11%	12%	-0.6 (-3.8, 2.6)	0.72
Birth < 32 weeks	5%	5%	-0.4 (-2.8, 1.7)	
Birth < 37 weeks*	23%	22%	1.3 (-3.0, 5.4)	

*Primary surrogate efficacy endpoint of Trial 002; Source: FDA 2019 AC Briefing Book

We conclude that Trial 003 failed to verify Makena's clinical benefit for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous PTB. This satisfies the ground for expedited withdrawal of approval under section 506(c)(3)(B) of the FD&C Act and 21 CFR 314.530(a)(1).

B. Makena Is Not Shown to Be Effective

Trials 002 and 003 contain the most robust and relevant data informing the efficacy of Makena for its intended use. Although Trial 002 met its surrogate endpoint, the unequivocal failure of Trial 003, a larger trial, to either show a benefit for neonatal outcomes or a treatment effect on the rate of preterm birth leads us to conclude that Makena has not been shown to be effective in improving neonatal outcomes or reducing the proportion of women delivering prematurely. To the latter point, most of the advisory committee members determined that, based on these two trials, there is no substantial evidence of effectiveness of Makena in reducing the risk of recurrent PTB. If these conflicting findings of Trials 002 and 003 were submitted at the same time in an NDA seeking approval for Makena, we would conclude that there is not substantial evidence of effectiveness of Makena for reducing the risk of recurrent PTB.

Trials 002 and 003 differed in region (Trial 002 was in the U.S. only whereas Trial 003 was an international trial), proportion of Black women (59% in Trial 002 vs. 7% in Trial 003), and other demographic and socioeconomic factors that potentially placed the study

[8] AMAG Pharmaceuticals Announces Topline Results from the PROLONG Trial Evaluating Makena, available at https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection/.

[9] See footnote 4 for details regarding the neonatal composite index. The percentages shown are the proportions of neonates experiencing at least one event comprising the neonatal composite index.

population of Trial 002 at higher risk of recurrent PTB compared to that of Trial 003. We conducted exploratory subgroup analyses by region, race, and other individual risk factors potentially important to the study outcomes that differed between the two trials to explore whether these differences could explain the disparate findings between Trials 002 and 003. These analyses did not show, nor even trend towards showing, that Makena improved neonatal outcomes or reduced the risk of recurrent PTB in women within or outside the U.S., Black or non-Black women, or in women with or without these other risk factors, such as having one or more than one prior spontaneous singleton PTB. Using the number of these risk factors for PTB as a proxy for different "risk" levels of having recurrent PTB, CDER's analyses found that the chance of having a PTB or a neonatal index event increased with increasing risk level. For women within a specific risk level, Makena did not have an effect over placebo. That is, Makena did not reduce adverse neonatal outcomes or the risk of PTB in women at lower or higher risk of recurrent PTB. Exploratory subgroup analyses of Trial 003 did not provide evidence of a treatment effect in any identified subgroup, including Black women or those in the "higher" risk group. These findings indicate that none of these risk factors influenced the effectiveness of Makena in Trial 003. Therefore, the varying prevalence of these risk factors in the populations of Trials 002 and 003 do not explain the differences in the efficacy findings between the two trials.

We thus conclude that, based on our analysis of the data, Makena is not shown to be effective for its intended use. This satisfies the ground for expedited withdrawal of approval under section 506(c)(3)(C) of the FD&C Act and 21 CFR 314.530(a)(6).

C. Other Reasons Weighing in Favor of Withdrawal of Approval

Beyond the fact that the statutory and regulatory standards for withdrawal of Makena's accelerated approval have been satisfied, the following additional considerations support withdrawal.

First, and most important, an approved drug product should only be permitted to remain on the market if the benefits of its continued availability outweigh its risks. When a postmarketing clinical study fails to verify clinical benefit, the benefit/risk assessment that supported initial approval of the product changes significantly; when this occurs, expedited withdrawal is generally in the public interest.[10] Makena's medical risks include thromboembolic disorders, allergic reactions, decreased glucose tolerance, fluid retention that may worsen maternal conditions such as pre-eclampsia, depression, and injection site adverse reactions. The risk of exposing treated pregnant women to these harms, in addition to false hopes, costs, and additional healthcare utilization[11] outweighs Makena's unproven benefit.

[10] See preamble to accelerated approval regulations, 57 FR 58942, 58955.

[11] Additional healthcare utilization includes burdens such as pregnant women needing to have clinic visits or home health visits for their weekly Makena injection or additional treatment for complications from injection site reactions.

Second, withdrawing Makena's approval upholds the regulatory integrity of accelerated approvals. Accelerated approval is an expedited pathway for approving promising new therapies for serious or life-threatening diseases based on an effect on a surrogate endpoint or intermediate clinical endpoint, where clinical benefit is verified after approval. However, it does not change the approval standard for drugs; it is rooted in the fundamental regulatory requirement that a drug product must be shown to be safe and effective to be approved for marketing in the United States. For the accelerated approval program to serve its purpose and not operate as a lower approval standard, FDA must be able to withdraw approvals when it determines, based on careful analysis of the data, that the confirmatory trial(s) failed to verify clinical benefit, or that, in consideration of all of the available data, the product can no longer be considered to have been shown to be effective for its approved indication.

III. Notice of Opportunity for a Hearing and Submission of Written Comments

Accordingly, we are hereby notifying AMAG, the holder of NDA 021945, and all holders of hydroxyprogesterone caproate ANDAs that reference NDA 021945, pursuant to sections 506, 505(j), and 505(e) of the FD&C Act and under 21 CFR 314.530(a) and (b) and 314.151, that CDER is proposing to withdraw the approval of NDA 021945. Upon withdrawal of NDA 021945, FDA would also withdraw the approvals of all ANDAs referencing NDA 021945. We are hereby notifying AMAG of an opportunity for a hearing on the withdrawal of NDA 021945, and we invite holders of ANDAs referencing NDA 021945 to submit comments, as described in section III.B of this letter.

A. Submissions by NDA Holder

In accordance with 21 CFR 314.530(b), the Acting Director of CDER hereby provides AMAG with notice of an opportunity for a hearing on CDER's proposal to withdraw approval of NDA 021945, the grounds for which are described in section II of this letter. AMAG may file a written request for a hearing within 15 days of receipt of this letter. If AMAG fails to file a written request for a hearing within 15 days, AMAG will thereby waive its opportunity for a hearing. The failure of an applicant to file a timely request for a hearing constitutes an election by that applicant not to avail itself of the opportunity to request a hearing concerning the action proposed and constitutes a waiver of any contentions concerning the legal status of that applicant's drug product. In such instance, FDA intends to withdraw approval of the affected application(s) and to take other appropriate action. Any new drug product marketed without an approved application is subject to regulatory action at any time.

If AMAG files a timely request for a hearing, the company must, within 30 days of receipt of this letter, submit data, information, and analyses to demonstrate that there is a genuine and substantial issue of material fact that requires a hearing. A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of material fact that requires a hearing. If it conclusively appears on the face of the data, information, and analyses submitted that there is no genuine and substantial issue of material fact, or if the required

data, information, and analyses are not provided, the hearing request will not be granted. If a hearing is granted, it will be conducted according to the procedures outlined in part 15 of FDA regulations (21 CFR part 15), as modified by § 314.530(e), and the Commissioner's decision will constitute final Agency action subject to judicial review (§ 314.530(f)).

The Division of Dockets Management is receiving USPS mail intermittently during the COVID-19 public health emergency. However, we encourage you to make submissions electronically. If you choose to make an electronic submission, please submit any requests for a hearing; any data, information, and analyses justifying a hearing; and any other comments identified with Docket No. FDA-2020-N-2029 to *http://www.regulations.gov*.

If you choose to make a paper submission under this notice of opportunity for a hearing, it must be filed in four copies. Please submit written requests for a hearing; any data, information, and analyses justifying a hearing; and any other comments identified with Docket No. FDA-2020-N-2029 to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Except for data and information prohibited from public disclosure, such as under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen on the Internet at *http://www.regulations.gov*.

B. Submissions by ANDA Holders

This letter serves as notice to the identified ANDA holders that the Agency proposes to withdraw approval of their applications upon withdrawal of approval of the listed drug. Consistent with § 314.151, the identified ANDA holders may submit written comments on this notice of opportunity for hearing. ANDA holders are required to submit comments within 30 days of receipt of this letter so that they may be considered by the Agency, along with any request and justification submitted by the NDA holder, in making a decision whether to hold a hearing. If a hearing is granted, those ANDA holders who submitted timely comments may participate in the hearing as nonparty participants.

If an ANDA holder has submitted timely comments but does not have an opportunity to participate in a hearing because a hearing is not held, the submitted comments will be considered by the Agency (§ 314.151(c)(1)). After considering all timely submissions, the Agency will issue an initial decision. The initial decision will respond to comments and contain the Agency's preliminary decision whether there are grounds to withdraw approval of the listed drug and the ANDAs. The initial decision will be sent to each ANDA holder that submitted comments (§ 314.151(c)(1)). ANDA holders to whom the initial decision is sent may, within 30 days of the issuance of the initial decision, submit

written objections (§ 314.151(c)(2)). The Agency may, at its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions (§ 314.151(c)(3)). If there are no timely objections, the initial decision will become final at the expiration of 30 days (§ 314.151(c)(4)). If timely objections are submitted, they will be reviewed and addressed in a final decision (§ 314.151(c)(5)).

If, upon withdrawal of approval of the listed drug, the Agency determines that the grounds for withdrawal of the listed drug are not applicable to one or more identified ANDAs, approval of those ANDAs will not be withdrawn (§ 314.151(d)). In all other cases, approval of the identified ANDAs will be withdrawn upon the issuance of a final decision concluding that the listed drug should be withdrawn. The final decision will be in writing and will constitute final Agency action, reviewable in a judicial proceeding (§ 314.151(c)(7)).

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If you choose to make a paper submission, it must be filed in four copies. Please submit written comments identified with Docket No. FDA-2020-N-2029 to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Except for data and information prohibited from public disclosure such as under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen on the Internet at http://www.regulations.gov.

IV. Authority and Contact Information

This notice is issued under § 314.530(b) and under authority delegated to the Director of CDER at FDA. If you have questions regarding this notice, please contact Kalesha Grayson at 301-796-0921.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002411843, cn=Patrizia A. Cavazzoni -S
Date: 2020.10.05 09:26:04 -04'00'

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research